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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,148	01/16/2004	Alexey L. Margolin	VPI/96-14 CON2	7188

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,148	MARGOLIN ET AL	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/13/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A preliminary amendment of 1/16/04 amended claims 31, 32, 35 and 44, and canceled claims 57-85.

Claims examined on the merits are 1-56, which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for crosslinking with a multifunctional crosslinking agent, does not reasonably provide enablement for other crosslinking agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification demonstrates the use of only a multifunctional crosslinking agent and does not describe steps and conditions for other forms of crosslinking.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear as to the form of crosslinked protein crystal claimed by defining the protein crystal in terms of a change in solubility that results from a change in environment that has no limitation as to range of environment change. Without knowing how much the environment is changed, it will be uncertain as to characteristics of the protein that render it insoluble, and allow it to become soluble with an environment change.

In claims 30 and 40, the meaning of "decontamination proteins" is uncertain.

Claims 39-44 are unclear as to how they further limit claims 1, 17 or 18 by requiring a delivery system since the system is required to contain only the crosslinked protein of claims 1, 17 or 18. The delivery system can be only the protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-44 and 46-56 are rejected under 35 U.S.C. 102(a) as anticipated by Navia et al (5,618,710).

The claims are drawn to crosslinked protein crystals and methods for preparation thereof wherein the crosslinked protein crystals can be changed from insoluble form to soluble form by a change in temperature, change in pH, change in chemical composition, change from concentrate to dilute form or change in shear force acting on the crystal.

Navia et al disclose crosslinked protein crystals that are inherently capable of being changed to soluble form by one or more of the changes claimed. The present claims encompass crosslinked protein crystals and methods for preparation thereof disclosed by Navia et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner

presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Navia et al.

The claim requires a detergent formulation containing the crosslinked protein crystal.

It would have been obvious to use a crosslinked enzyme crystal such as a protease produced as disclosed by Navia et al in a detergent formulation as required by claim 45 since it is conventional to use enzymes such as proteases in detergent formulations and Navia et al disclose using crosslinked enzyme crystals for uses where enzymes are conventionally used.

Claim Rejections - 35 USC § 103

Claims 1-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Navia et al in view of Kausch et al (5,508,164) and Neville et al (5,066,490).

Navia et al is described above.

Kausch et al disclose using disulfide crosslinking agents for reversible immobilization (col 6, lines 52-68).

Neville et al disclose using a reversible crosslinking agents for linking an amino group containing substance to a group on a second compound so the crosslinking agent can be cleaved to release the substance.

It would have been obvious to use as the crosslinking agent of Navia et al a reversible crosslinking agent as disclosed by Kausch et al and Neville et al to enable removing the reversible crosslinking agent by a change in environment to render the crosslinked protein soluble and make the protein non-immobilized. The conditions of dependent claims and methods of preparing the crosslinked protein would have been obvious from Navia et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,140,475. Although the conflicting claims are

not identical, they are not patentably distinct from each other because crosslinked protein crystals that dissolve as presently claimed and method for preparation thereof as presently claimed would have been obvious from the method of the claims of the patent that produces crosslinked protein crystals that dissolve as a result of a change in environment that can be the same as required by the present claims.

Double Patenting

Claims 1-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,618,710 in view of claims 1-19 of Margolin et al (6,140,475), and if necessary in further view of Neville et al (5,066,490) and Kausch et al (5,508,164). It would have obvious to form the crosslinked protein of the claims of patent so that it will become soluble by a change in environment as disclosed by the claims of Margolin et al when changing a protein from insoluble to soluble form by a change in environment. If needed, Neville et al and Kausch et al would have suggested a reversible crosslinking agent for the type of reasons set forth above, and it would have been obvious to use a reversible crosslinking agent as the crosslinking agent of the patent claims to obtain reversible immobilization as suggested by Neville et al and Kausch et al by making an environment change that removes the crosslinking agent. Reversing immobilization will render the protein soluble.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 751-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
7/2/05